No. 2023-1169

United States Court of Appeals for the Federal Circuit

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD,
Plaintiffs-Appellants

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC,
Defendants-Appellees

HEALTH NET LLC,
Defendant

Appeal from the U.S. District Court for the District of Delaware, Case No. 1:20-cv-01630-RGA-JLH, Judge Richard G. Andrews

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PETITION FOR REHEARING EN BANC

EIMERIC REIG-PLESSIS
Winston & Strawn LLP
101 California Street
San Francisco, CA 94111
(415) 591-1000

ALISON M. KING
Winston & Strawn LLP
35 W. Wacker Drive
Chicago, IL 60601
(312) 558-5600

CHARLES B. KLEIN
CLAIRE A. FUNDAKOWSKI
Winston & Strawn LLP
1901 L Street NW
Washington, DC 20036
(202) 282-5000

Counsel for Defendants-Appellees Hikma Pharmaceuticals USA Inc., Hikma Pharmaceuticals PLC

CERTIFICATE OF INTEREST

Undersigned counsel certifies that the following information is accurate and complete to the best of counsel's knowledge:

1. **Represented Entities.** Fed. Cir. R. 47.4(a)(1): "The full name of every entity represented in the case by the counsel filing the certificate."

   Hikma Pharmaceuticals USA Inc.
   Hikma Pharmaceuticals PLC

2. **Real Party in Interest.** Fed. Cir. R. 47.4(a)(2): "For each entity, the name of every real party in interest, if that entity is not the real party in interest."

   N/A

3. **Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3): "For each entity, that entity's parent corporation(s) and every publicly held corporation that owns ten percent (10%) or more of its stock."

   Hikma Pharmaceuticals USA Inc. is an indirect wholly owned subsidiary of ***Hikma Pharmaceuticals, PLC***, which is a publicly held corporation. ***Hikma Pharmaceuticals, PLC*** does not have a parent corporation, and no publicly held corporation owns 10% or more of its stock.

4. **Legal Representatives.** Fed. Cir. R. 47.4(a)(4): "The names of all law firms, partners, and associates that have not entered an appearance in the appeal, and (A) appeared for the entity in the lower tribunal; or (B) are expected to appear for the entity in this court."

   Heyman Enerio Gattuso & Hirzel LLP: Dominick T. Gattuso

5. **Related Cases.** Fed. Cir. R. 47.4(a)(5): "An indication as to whether there are any related or prior cases, other than the originating case number(s), that meet the criteria under Federal Circuit Rule 47.5."

   No

6. Organizational Victims and Bankruptcy Cases. Fed. Cir. R. 47.4(a)(6): "All information required by Federal Rule of Appellate Procedure 26.1(b) and (c) that identifies organizational victims in criminal cases and debtors and trustees in bankruptcy cases."

N/A

August 22, 2024

/s/ Charles B. Klein
CHARLES B. KLEIN
Counsel of Record for
Defendants-Appellees

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CIRCUIT RULE 35(b)(2) STATEMENT

Based on my professional judgment, I believe the panel decision is contrary to the following precedents of the Supreme Court and this Court:

> *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011); *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021); *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315 (Fed. Cir. 2016); *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015); *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201 (Fed. Cir. 2014); *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012); *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293 (Fed. Cir. 2006); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003).

Based on my professional judgment, I believe this appeal requires an answer to precedent-setting questions of exceptional importance:

1. Can a patentee state a claim that a defendant "actively induces infringement" of a patented method under 35 U.S.C. § 271(b) without identifying any alleged statement by the defendant that even mentions, let alone encourages, practicing the claimed method?

2. Where it is undisputed that a generic drugmaker has "carved out" a patented method of use from its labeling under 21 U.S.C. § 355(j)(2)(A)(viii), does the generic drugmaker induce infringement of the patented method by (a) referring to its product as a "generic version" of a branded drug approved for the patented method; and (b) quoting sales figures for the branded product—without mentioning the patented method?

August 22, 2024

/s/ Charles B. Klein
CHARLES B. KLEIN
Counsel of Record for Defendants-Appellees

INTRODUCTION

Hikma seeks rehearing en banc of a panel decision that conflicts with this Court's precedent on induced infringement and eviscerates a statutory mechanism that Congress enacted to expedite access to generic drugs. The panel held that Hikma's description of its generic drug as a "generic version" of a branded drug, along with references to annual sales of the branded drug, was sufficient to plead induced infringement of a patented method that Hikma undisputedly carved out of its generic product label. Commentators warn that the decision will "diminish hope"[1] and "create[] uncertainty in the sale and marketing of generic drugs,"[2] while "[b]randed pharmaceutical manufacturers may be emboldened to sue after launch"[3] by generic competitors—defeating a central purpose of the Hatch-Waxman Act to achieve patent certainty before market entry. Left uncorrected, the decision will deter generic competition and expand the risk of inducement liability even beyond the pharmaceutical industry.

Less than three years ago, this Court split sharply over whether to rehear its decision in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320

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[1] https://www.duanemorris.com/alerts/federal_circuit_revives_induced_infringement_suit_against_generic_pharma_when_skinny_label_0724.html

[2] https://www.law360.com/ip/articles/1863857/the-fed-circ-in-june-more-liability-for-generic-drug-makers

[3] https://www.ipupdate.com/2024/07/is-pleading-generic-enough-to-plead-inducement/

(Fed. Cir. 2021) ("*GSK*"), *rehearing denied*, 25 F.4th 949 (Fed. Cir. 2022) ("*GSK Rehearing*"). A divided panel revived an induced-infringement verdict against a generic drugmaker that invoked Hatch-Waxman's "section viii" to "carve out" a patented use, marketing its generic product under a "skinny label." *GSK*, 7 F.4th at 1327-28. The majority reversed Judge Stark's judgment of noninfringement and held the generic's "label instructed the method of use claimed in the [asserted] patent and thus was not a skinny label." *Id*. at 1328. Over three dissents, the en banc Court denied rehearing. *GSK Rehearing*, 25 F.4th at 953-60. The concurrence made clear, however, that *GSK*'s holding was "narrow and fact dependent." *Id*. at 951. As proof, the concurrence cited the district court's decision in *this* case (*id*.), which dismissed Amarin's complaint for "fail[ing] to plead inducement based on Hikma's label or public statements" (Appx9). Yet the panel here reversed that decision—drastically expanding *GSK*'s holding.

Like *GSK*, this case involves a skinny label. Unlike in *GSK*, however, Hikma's label admittedly *is* "skinny enough." Op. 12. Amarin's asserted patents require using the drug icosapent in specific patient populations for "reducing risk of cardiovascular death" or for "reducing occurrence of a cardiovascular event" with a second drug (a statin). Op. 8. The panel agreed Hikma's skinny "label does not, as a matter of law, recommend, encourage, or promote [either] infringing use." Op. 16 (cleaned up). But it found plausible inducement because Hikma called its

product a "generic version" of Amarin's Vascepa and quoted Vascepa's annual sales. Op. 5-7, 18. The panel found these statements sufficient to plead "instruction or encouragement to prescribe [Hikma's] drug for *any* of the approved uses of icosapent"—including cardiovascular ("CV")-risk reduction that appears only in *Amarin's* Vascepa label—even though Hikma's statements never *mention* CV risk, much less using icosapent to reduce it. Op. 18 (emphasis in original).[4]

By allowing inducement claims to proceed without any statement by Hikma encouraging the claimed methods, the decision breaks with longstanding precedent and the inducement statute itself, which limits liability to one who "*actively* induces infringement." 35 U.S.C. § 271(b). The panel's theory assumes physicians plausibly will (1) read Hikma's press releases, (2) infer they can use Hikma's "generic version" for all approved uses of Vascepa, and (3) consult Amarin's Vascepa label—not Hikma's label—to determine those uses. At most, this is a theory of *passive* inducement. Amarin failed to plead that Hikma *actively* induced physicians to use its product for CV uses. Hikma's public statements do not mention Vascepa's label, and Vascepa-label instructions cannot be imputed to Hikma: Inducement requires "*the defendants' actions* led to direct infringement"—

[4] All emphases in this petition are added unless otherwise noted.

not the actions of others. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1331 (Fed. Cir. 2016) (quotation omitted).

The decision also conflicts with *GSK*'s holding that "simply calling a product a 'generic version'" is not inducement. 7 F.4th at 1336. And, by crediting *sales figures* as plausible inducement, the decision contradicts precedent holding that patentees cannot allege inducement based merely on "market realities"—a result that "would, in practice, vitiate" section viii. *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012).

Even before the decision, commentators viewed Amarin's lawsuit as "a prototype for future litigation" that "may delay or deter generics from entering the market."[5] The decision all but ensures that result. *Every* generic drug, by definition, is "a generic version" of another product, and market-size discussions are practically unavoidable in communications to investors and the public. If this were enough to plead inducement, *every* skinny label would be litigated.

That this case is at the pleadings stage does not diminish its impact. "To survive a motion to dismiss, a complaint must contain *sufficient factual matter*, accepted as true, …. that allows the court to draw the *reasonable inference* that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662,

[5] S. Tu & C. Duan, *Pharmaceutical Patent Two-Step: The Adverse Advent of Amarin v. Hikma Type Litigation*, 12 NYU J. Intell. Prop. & Ent. L. 1, 17-18 (2022).

678 (2009). This "plausibility standard" requires "more than a sheer possibility" (*id*.)—for good reason. As the Supreme Court recognized: "It is no answer to say that a claim … can, if groundless, be weeded out early in the discovery process" or at "summary judgment." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007) (quotation omitted). Discovery is notoriously expensive, and "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases before reaching those proceedings." *Id*. at 558-59.

That concern is vital in the generic-drug industry, where razor-thin profit margins make litigation a powerful deterrent. Even unsuccessful "lawsuits increase the potential costs for competitors to enter the market or delay the entry of" generic drugs.[6] As the Solicitor General foresaw in *GSK*, mere "*potential* for inducement liability in these circumstances may significantly deter use of the section viii pathway." Brief for the United States as Amicus Curiae Supporting Respondents, *Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC*, 143 S. Ct. 2483 (2023) (No. 22-37), 2023 WL 2717391, at *22 (emphasis in original).

The Court should grant rehearing en banc.

[6] Tu & Duan, *supra* note 5 at 18.

STATEMENT OF THE CASE

A. Congress creates a regulatory pathway for generic drugmakers to carve out patented uses, expediting access to generic drugs.

Section viii is a limited but important exception to the general rule that generic labels must be "the same as the labeling approved for" branded drugs. 21 U.S.C. § 355(j)(2)(A)(v). "[W]hen the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug," section viii permits "labeling for the generic drug that 'carves out' from the brand's approved label the still-patented methods of use." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012) (citing 21 U.S.C. § 355(j)(2)(A)(viii)). To ensure generic drugs "can quickly come to market," Congress "contemplate[d] that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Id*. at 415.

B. Hikma follows the statutory framework and fully carves out Amarin's patented use for reducing cardiovascular risk.

This is Amarin's second attempt to block competition from Hikma. FDA first approved icosapent to treat severe hypertriglyceridemia ("SH") (triglycerides ≥500 mg/dL). Op. 3. When Hikma sought FDA approval for generic icosapent, Amarin sued, asserting six patents on using icosapent to treat SH. Op. 4 n.4. Hikma successfully invalidated those patents. *Id*.

While that case was pending, FDA approved a second indication to reduce CV risk. Op. 3. Amarin obtained patents, including those asserted here, claiming

icosapent's use for "reducing risk of cardiovascular death" or (with a statin) "reducing occurrence of a cardiovascular event" in specific patient populations with triglycerides ≥150 mg/dL. Op. 8. Under section viii, Hikma's label carves out the CV indication, keeping only the SH indication. *Id*.

Amarin sued anyway, within a month of Hikma's launch. Op. 7. Amarin's complaint admits Hikma's product "is not FDA-approved for the CV Indication" and approved for "only the [SH] Indication." Appx521-522. Nevertheless, Amarin alleges Hikma's statements in three pre-launch press releases and Hikma's website induced infringement of Amarin's CV patents.[7] Op. 5-7; Appx709-713; Appx613; Appx820. These press releases called Hikma's product a "generic version" of Vascepa. *Id*. Two press releases quoted Vascepa's annual sales. *Id*. A fourth press release announcing Hikma's product launch quoted the SH indication and included a disclaimer: "Hikma's product is *not* approved for any other indication for the reference listed drug VASCEPA®." Op. 7; Appx715-717. Hikma's website stated its product is in the "Therapeutic Category: Hypertriglyceridemia" and is "AB" rated (i.e., "therapeutically equivalent to a branded drug"), while warning that it "is indicated for fewer than all approved indications of the Reference Listed Drug." Op. 7. None of Hikma's statements

[7] Amarin also alleged Hikma's skinny label induced infringement, but the panel did not adopt that theory. Op. 16.

mention Vascepa's CV indication or CV risk, let alone using icosapent with a statin to reduce such risk.

C. The district court follows precedent, dismissing Amarin's suit.

The district court granted Hikma's motion to dismiss for failure to state a claim. Appx1-9. The court found Hikma's "label does not instruct CV risk reduction," as Amarin's CV patents require. Appx7.

Turning to Hikma's press releases, the district court cited *GSK* to find "Hikma's advertising of icosapent ethyl as the 'generic equivalent' of Vascepa does not expose Hikma to liability." Appx8 (citing *GSK*, 7 F.4th at 1335 n.7). The court reasoned that, at most, quoting Vascepa's sales "might be relevant to intent," but it is not "an inducing act" encouraging infringement. *Id*.

For purposes of Hikma's motion, the district court adopted Amarin's theory that Hikma's reference to "Hypertriglyceridemia" on its website is broader than SH and overlaps with the CV indication's patient population. Appx8. But the court found this "does not rise to the level of encouraging, recommending, or promoting taking Hikma's generic for the reduction of CV risk." *Id*. Amarin thus failed to plead induced infringement. *Id*.

D. The panel reverses without citing any alleged statement by Hikma that encourages infringement.

The panel reversed. It agreed Hikma's "label does not, as a matter of law, recommend, encourage, or promote an infringing use." Op. 16 (cleaned up). But

the panel found "it at least plausible that a physician could read Hikma's press releases—touting sales figures attributable largely to an infringing use, and calling Hikma's product the 'generic version' of a drug that is indicated 'in part' for the SH indication—as an instruction or encouragement to prescribe that drug for *any* of the approved uses of icosapent ethyl, particularly where the label suggests that the drug may be effective for an overlapping patient population." Op. 18 (emphasis in original). The panel further found that the reference to "Hypertriglyceridemia" on Hikma's website plausibly induced infringement despite "an express disclaimer that Hikma's product is FDA-approved for fewer than all uses of Vascepa." Op. 18 & n.6.

The panel did not identify a single statement by Hikma that even mentions, much less encourages, administering icosapent for "reducing risk of cardiovascular death" or "reducing occurrence of a cardiovascular event" when taken with a statin, as required by Amarin's CV patents. Op. 8.

ARGUMENT

I. The panel decision conflicts sharply with precedent on both induced infringement in general and generic drugs in particular.

The Court should rehear this case en banc because the panel decision contradicts precedent and dramatically expands the scope of active inducement.

A. The decision contradicts longstanding precedent that requires active steps by the defendant encouraging infringement.

Congress limited inducement liability to one who "*actively* induces infringement." 35 U.S.C. § 271(b). "[T]he adverb 'actively' suggests that the inducement must involve the taking of *affirmative steps* to bring about the desired result" (*Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011))—i.e., "clear expression or other affirmative steps taken to foster infringement'" (*DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305-06 (Fed. Cir. 2006)).

Mere "possible infringement by others does not amount to inducement; specific intent *and action* to induce infringement must be proven." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). Thus, the statute requires "'*active steps* taken to encourage direct infringement,'" with "*instructions teach*[*ing*] an infringing use." *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 630-31 (Fed. Cir. 2015) (quotation omitted). Even "describing an infringing mode is not" enough for liability; inducement requires "*recommending, encouraging, or promoting* an infringing use, or suggesting that an infringing use *should* be performed." *Id*. at 631 (cleaned up). If a defendant's statements "do not *specifically* encourage [an infringing] use," they "do not encourage infringement" under § 271(b). *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1339-40 (Fed. Cir. 2019).

As with direct infringement, every limitation counts: "In order to prove induced infringement, the patentee must show that the alleged infringer performs, or induces another party to perform, *every single step in the method*." *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1219 (Fed. Cir. 2014).

Critically, the indirect infringer's *own* actions—not those of other parties—must suffice to actively induce infringement. In *Power Integrations*, this Court reversed an inducement verdict because the jury was instructed that "infringement need not have been actually caused by the alleged inducer's actions." 843 F.3d at 1332 (alteration omitted). The Court reaffirmed that inducement requires "*the defendants' actions* led to direct infringement." *Id*. at 1331 (quotation omitted).

The decision here cannot be reconciled with these precedents. Amarin's asserted patents require using icosapent for "reducing risk of cardiovascular death" or, with statin use, "reducing occurrence of a cardiovascular event." Op. 8. The panel recognized this claim language is "limiting, such that infringement of the claims *requires* use of icosapent ethyl to reduce cardiovascular risk." Op. 9 n.5. Yet the panel decision identifies no statement by Hikma that actively induces (recommends, encourages, or promotes) using icosapent to reduce CV risk, much less with a statin. Amarin pleaded no such statement by Hikma.

Effectively, the decision allows *Amarin's* statements in its Vascepa label to supply the inducing acts. According to the panel, calling Hikma's product a

"generic version" and quoting Vascepa's sales figures is plausibly "an instruction or encouragement to prescribe [Hikma]'s drug for *any* of the approved uses of icosapent" (Op. 18)—including the CV indication that appears *only* on Amarin's Vascepa label—even though "Hikma's approved label refers only to the SH indication" (Op. 5). Likewise, the decision finds plausible "encouragement to use the generic for purposes beyond the approved SH indication" (Op. 19) yet never identifies any inducement *by Hikma* for the claimed CV uses.

At most, the decision credits the argument that Hikma's "label suggests that the drug may be effective for an overlapping patient population" with elevated triglycerides. Op. 18. But it is undisputed that *nothing* in the label *or* Hikma's public statements instructs—or even mentions—using icosapent *to reduce CV risk*. In finding plausible inducement, the decision violates settled precedent that "vague label language cannot be combined with speculation about how physicians may act to find inducement." *Takeda*, 785 F.3d at 632 (addressing alleged inducement under § 271(b), outside the Hatch-Waxman context).

The panel decision radically expands inducement liability far beyond § 271(b)'s limits, creating "a very permissive pleading standard for induced infringement" even "outside of just the pharmaceutical context."[8] The Court

[8] *Supra* note 2.

should grant rehearing to reconcile this case with precedent requiring active steps by the accused indirect infringer.

B. The decision contradicts precedent that calling a product a "generic version" and relying on "market realities" of generic substitution cannot establish induced infringement.

Apart from broadening inducement liability beyond its statutory limits, the panel decision contradicts the majority opinion in *GSK*, which rejected the dissent's criticism that "simply calling a product a 'generic version' or 'generic equivalent'[] is now enough." 7 F.4th at 1336. The majority assured "[t]hat is not our holding or the facts." *Id*. But that *is* the holding—and the facts—here.

The panel found plausible inducement in press releases that "consistently referred to Hikma's product as a 'generic equivalent to Vascepa®,' 'generic Vascepa®,' or 'Hikma's generic version of Vascepa®.'" Op. 17. Yet calling a product a "generic version" cannot be enough to induce infringement, or else *every* generic drug with a skinny label would induce infringement of *every* patent covering its branded equivalent. Congress itself refers to generic drugs as the "'generic version' … [of a] reference listed drug" (21 U.S.C. § 353d(a)(3)), as does the Supreme Court (*Caraco*, 566 U.S. at 404, 409, 415), this Court (*Grunenthal*, 919 F.3d at 1338-39), and the Department of Health and Human Services (42 C.F.R. § 423.132(a)). As commentators warn, stating that Hikma's product is "a generic equivalent of Vascepa …. accurately reflects [its] FDA approval," yet the

decision "suggests that such accurate statements regarding regulatory approval may constitute inducement."[9]

To be sure, the panel decision says "Hikma did much more than call its product a 'generic version' of Vascepa." Op. 20. But the "much more" here amounts to reporting "sales figures." Op. 18. Even assuming sales figures could imply *intent* to substitute Hikma's generic product for all Vascepa prescriptions (a stretch), that is not enough because the law requires both "specific intent *and action* to induce infringement." *Warner-Lambert*, 316 F.3d at 1364.

Even assuming Hikma *knew* its product would be prescribed to reduce CV risk, "mere knowledge of possible infringement by others does not amount to inducement." *Id*. "[W]ithout inducement by [Hikma]," such "knowledge is legally irrelevant." *Id*. In *Takeda*—a post-launch case outside the Hatch-Waxman context—this Court recognized that Congress "designed [section viii] to enable the sale of drugs for non-patented uses *even though this would result in some off-label infringing uses*." 785 F.3d at 631. Post-launch inducement "only exists where there is evidence that goes *beyond* a product's characteristics or the knowledge that it may be put to infringing uses." *Id*. at 630 (citation omitted).

[9] *Supra* note 2.

In *AstraZeneca*, this Court rejected nearly identical reliance on the "market realities" of generic substitution "for all indications" as "unpersuasive." 669 F.3d at 1380. "[I]f accepted, these speculative arguments would allow a pioneer drug manufacturer to maintain de facto indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of using the compound"—"contrary to the statutory scheme." *Id*.

To the extent the panel faulted Hikma for not including an "AB-rated" statement in its press releases (Op. 19), that is not a plausible basis for induced infringement. First, Amarin never alleged a physician would interpret the phrase "AB-rated" more narrowly than "generic version." Instead, it alleged AB ratings encourage "substitution … regardless of whether the generic drug label includes all the indications in the branded drug labeling." Appx533 (¶ 129). Second, the *absence* of a "clear statement" that Hikma's product "will be used for [SH] only" is not *active* inducement: Amarin must plead Hikma "took affirmative steps to induce, not affirmative steps to make sure others avoid infringement." *Takeda*, 785 F.3d at 632 n.4. Third, there is no material difference between the phrases "AB-rated" and "generic version"—both phrases are "vague" as to infringement and "cannot be combined with speculation about how physicians may act to find inducement." *Id.* at 632. Hikma's generic icosapent is both "AB-rated" and a

"generic version" of a branded drug. Neither statement says anything about the scope of its FDA-approved indications.[10]

In short, calling a product a "generic version" and recognizing the "market realities" of generic substitution cannot suffice to plead induced infringement.

II. The panel decision nullifies labeling carve-outs under section viii and will severely harm generic competition absent rehearing.

If the panel decision stands, section viii will be a dead letter. The facts deemed sufficient here exist in *every* skinny-label case. Under the panel's logic, a generic company's CEO announcing a generic product and quoting a branded drug's market size to shareholders on an earnings call without explicitly warning that the generic drug is AB-rated would invite a lawsuit for induced infringement. This will, "in practice, vitiate" section viii (*AstraZeneca*, 669 F.3d at 1380), and will effectively ban pre-approval communications about generic drugs, which do not receive an AB-rating until they are approved by FDA.

Congress passed section viii so generics could *avoid* pre-suit litigation under Hatch-Waxman and "quickly come to market." *Caraco*, 566 U.S. at 415. Instead, the panel decision makes skinny labels *riskier* than Hatch-Waxman challenges, with massive exposure to lost-profits damages. Making matters worse, the panel

[10] Equivalency is determined on a product-by-product basis, not indication-by-indication basis. *E.g.*, 35 U.S.C. § 355(j)(2)(A)(iv) (requiring ANDAs to include "information to show that the new *drug* is bioequivalent to the listed *drug*").

"provided little guidance about what a generic label should include to help avoid inducement, and generally left that question unresolved."[11] Facing such risks, generic companies "simply won't play" because "lost profits to the brand can dwarf whatever profits a generic could make." *GSK Rehearing*, 25 F.4th at 955 (Prost, J., dissenting, joined by Dyk and Reyna, JJ.).

The panel dismissed these concerns as "inflated" because of the "stage of proceedings" on a motion to dismiss. Op. 20. True, Amarin's case is weak, and it is unlikely to succeed. But the precedential harm will already be done. The threat of protracted litigation through fact and expert discovery is enough to deter generic competition. By one estimate, "the average cost to defend an infringement lawsuit in the United States is roughly $3.5 million."[12] Post-launch, skinny-label litigation effectively doubles the cost; Hikma needs to defend a second lawsuit despite winning its Hatch-Waxman case.

Generic drugmakers already "face difficult economic conditions that stem from low and/or unpredictable sales volumes, prices, and profit margins for many generic drugs."[13] Doubling litigation costs and adding the risk of lost-profits

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[11] *Supra* note 2.

[12] G. Day & S. Udick, *Patent Law and the Emigration of Innovation*, 94 Wash. L. Rev. 119, 125 (2019).

[13] U.S. Dept. Health & Human Services, *Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States* 3 (2024),

damages—however remote—will "deter potential market entrants."[14] That is why the federal government, in supporting certiorari in *GSK*, warned that even "the *potential* for inducement liability in these circumstances may significantly deter use of the section viii pathway, even if such liability is rarely imposed." *Teva*, 2023 WL 2717391, at *22 (emphasis in original).

Under the panel decision, no skinny label is safe. Even with slim chances of success, patentees will reflexively file suit if they can get past motions to dismiss based on vague and practically unavoidable statements that an accused product is a "generic version" competing for a branded product's sales. The twin threats of litigation expense and lost-profits damages will deter generic companies from invoking section viii, defeating Congressional intent to lower drug prices and harming patients and healthcare providers.

CONCLUSION

The Court should grant rehearing en banc. At a minimum, given the Solicitor General's support for certiorari in *GSK* on related grounds, the Court should invite the government's views. *See Guarantee Co. of N. Am., USA v. Ikhana, LLC*, No. 18-1394, Dkt. 62 (Fed. Cir. Jan. 7, 2020).

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https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf

[14] *Id*.

Respectfully submitted,

/s/ Charles B. Klein

EIMERIC REIG-PLESSIS
Winston & Strawn LLP
101 California Street
San Francisco, CA 94111
(415) 591-1000
ereigplessis@winston.com

ALISON M. KING
Winston & Strawn LLP
35 W. Wacker Drive
Chicago, IL 60601
(312) 558-5600
amking@winston.com

CHARLES B. KLEIN
CLAIRE A. FUNDAKOWSKI
Winston & Strawn LLP
1901 L Street NW
Washington, DC 20036
(202) 282-5000
cklein@winston.com
cfundakowski@winston.com

Counsel for Defendants-Appellees Hikma Pharmaceuticals USA Inc., Hikma Pharmaceuticals PLC

August 22, 2024

ADDENDUM

United States Court of Appeals for the Federal Circuit

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD.,
Plaintiffs-Appellants

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC,
Defendants-Appellees

HEALTH NET LLC,
Defendant

2023-1169

Appeal from the United States District Court for the District of Delaware in No. 1:20-cv-01630-RGA-JLH, Judge Richard G. Andrews.

Decided: June 25, 2024

NATHAN K. KELLEY, Perkins Coie LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by NATHANAEL D. ANDREWS.

CHARLES B. KLEIN, Winston & Strawn LLP, Washington, DC, argued for defendants-appellees. Also

represented by CLAIRE A. FUNDAKOWSKI; ALISON MICHELLE KING, Chicago, IL; EIMERIC REIG-PLESSIS, San Francisco, CA.

SARA WEXLER KOBLITZ, Hyman, Phelps & McNamara, Washington, DC, for amicus curiae Association for Accessible Medicines.

Before MOORE, *Chief Judge*, LOURIE, *Circuit Judge*, and ALBRIGHT, *District Judge*.[1]

LOURIE, *Circuit Judge.*

Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Mochida Pharmaceutical Co., Ltd. (collectively, "Amarin") appeal from a decision of the United States District Court for the District of Delaware granting Hikma Pharmaceuticals USA Inc.'s and Hikma Pharmaceuticals PLC's (collectively, "Hikma") motion to dismiss Amarin's complaint for failure to state a claim. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 578 F. Supp. 3d 642 (D. Del. 2022) ("*Decision*").[2] Because Amarin's allegations against Hikma plausibly state a claim for induced infringement, we reverse.

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[1] Honorable Alan D Albright, District Judge, United States District Court for the Western District of Texas, sitting by designation.

[2] In the same decision, the court denied Health Net LLC's motion to dismiss the complaint for failure to state a claim for induced infringement. *See Decision*, 578 F. Supp. 3d at 643. Amarin's claims against that defendant, which appear to have settled, *see* J.A. 35, are therefore not at issue in this appeal.

BACKGROUND

I

Amarin markets and sells icosapent ethyl, an ethyl ester of an omega-3 fatty acid commonly found in fish oils, under the brand name Vascepa®. In 2012, the U.S. Food and Drug Administration ("FDA") approved Vascepa for the treatment of severe hypertriglyceridemia ("the SH indication"), a condition in which a patient's blood triglyceride level is at least 500 mg/dL. As part of its labeling for Vascepa, Amarin included an express "limitation of use," disclosing that "[t]he effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined." J.A. 650 ("the CV Limitation of Use"). But observing that clinical testing data demonstrated that Vascepa was capable of lowering triglyceride levels without increasing "bad" cholesterol (*i.e.*, LDL-C), Amarin continued its research into potential cardiovascular uses of the drug.

In 2019, following the success of Amarin's additional research and clinical trials, the FDA approved Vascepa for a second use: as a treatment to reduce cardiovascular risk (*i.e.*, myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization) in patients having blood triglyceride levels of at least 150 mg/dL ("the CV indication"). Upon receiving that approval, Amarin added the CV indication to its label and removed the CV Limitation of Use. *Compare* J.A. 650 (pre-CV indication approval), *and* J.A. 663 (same), *with* J.A. 635 (post-CV indication approval). It also timely listed U.S. Patent 9,700,537 ("the '537 patent") and U.S. Patent 10,568,861 ("the '861 patent") (collectively, "the asserted patents"),

which each claim methods directed to the CV indication, in the Orange Book.[3]

In 2016, when Vascepa was still only approved for the SH indication, Hikma submitted an Abbreviated New Drug Application ("ANDA") for approval of its generic icosapent ethyl product.[4] That ANDA remained pending in 2019 when the FDA approved the use of icosapent ethyl for the CV indication. At that juncture, Hikma was required to either amend its proposed label to match the revised Vascepa label including the CV indication and corresponding information, *see* 21 U.S.C. § 355(j)(2)(A)(vii), or file a "section viii statement" to "carve-out" that indication, *see*

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[3] The '537 patent is assigned to Mochida Pharmaceutical Co., Ltd. and exclusively licensed to Amarin Pharma, Inc. J.A. 512. The '861 patent is assigned to Amarin Pharmaceuticals Ireland Limited and exclusively licensed to Amarin Pharma, Inc. *Id.* at 513. In its operative complaint, Amarin also asserted U.S. Patent 8,642,077 against Hikma, but the parties' dispute as to that patent has been resolved. *See* Amarin Br. at 12 n.2.

[4] As part of its ANDA, Hikma submitted a paragraph IV certification averring that Amarin's then-Orange Book listed patents directed to the treatment of severe hypertriglyceridemia were invalid or would not be infringed by the manufacture, use, or sale of Hikma's generic product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Based on the ANDA filing, Amarin sued Hikma in the United States District Court for the District of Nevada for patent infringement ("the Nevada litigation"). Following a bench trial, and subsequent appeal, Amarin's asserted severe hypertriglyceridemia-related patents were held invalid as obvious. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 449 F. Supp. 3d 967, 1015 (D. Nev.), *aff'd summarily*, 819 F. App'x 932 (Fed. Cir. 2020). Those patents are therefore not at issue here.

id. § 355(j)(2)(A)(viii). Hikma opted for the latter and submitted a statement seeking FDA approval only for uses not covered by Amarin's newly listed CV indication patents. In other words, Hikma sought the FDA's approval of a "skinny label" for its generic product that would include only the SH indication and not the CV indication. The FDA approved Hikma's ANDA, including its proposed skinny label, on May 21, 2020.

Hikma's approved label refers only to the SH indication in the "Indications and Usage" section. J.A. 694 (providing that the drug is indicated only "as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia"). It further identifies potential side effects, stating that people with cardiovascular disease or diabetes with a risk factor for cardiovascular disease may experience "[h]eart rhythm problems (atrial fibrillation and atrial flutter)." *Id.* at 704–05. And it acknowledges that "[m]edicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet." *Id.* at 705. Like the current Vascepa label, Hikma's approved label does not include the CV Limitation of Use that was present on the Vascepa label during the time when icosapent ethyl was approved for only the SH indication. *Compare id.* at 694 (Hikma label), *and id.* at 635 (current Vascepa label), *with id.* at 650 (Vascepa label pre-CV indication approval). Although Hikma's original proposed label included the CV Limitation of Use, Hikma later amended the label to remove that limitation around the same time it submitted its section viii statement carving out the uses covered by the asserted patents.

Throughout 2020, Hikma issued a series of press releases regarding its efforts to provide a generic icosapent ethyl product. First, in March, it publicly announced the favorable district court outcome in the Nevada litigation against Amarin regarding the SH indication ("the March 2020 Press Release"). J.A. 709; *see supra* note 4. That press release referred to Hikma's product as the "generic

version" of Vascepa, which it described as "medicine that is indicated, in part, [to treat] severe (≥ 500 mg/dL) hypertriglyceridemia." J.A. 709. It also provided sales data for Vascepa, stating that sales of the product in the United States "were approximately $919 million in the 12 months ending February 2020." *Id.*

Then, the day after the FDA granted Hikma's ANDA, Hikma issued a press release announcing the approval ("the May 2020 Press Release"). *Id.* at 613. The press release stated that Hikma had received FDA approval for its icosapent ethyl tablets, "the generic equivalent to Vascepa®." *Id.* It further included a quote from Hikma's President of Generics that "[t]he approval for our generic version of Vascepa® is an important milestone towards bringing this product to market." *Id.*

A little over three months later, on September 3, 2020, Hikma issued a press release announcing the positive outcome in the appeal of the Nevada litigation regarding its alleged infringement of Amarin's SH indication patents ("the September 2020 Press Release"). J.A. 712; *see supra* note 4. Similar to the prior press releases, the September 2020 Press Release referred to Hikma's product as "Hikma's generic version of Vascepa®" and "generic Vascepa®." J.A. 712. And, like the March 2020 Press Release, it further provided the following description of Vascepa:

> Vascepa® is a prescription medicine that is indicated, in part, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. According to IQVIA, US sales of Vascepa® were approximately $1.1 billion in the 12 months ending July 2020.

Id. The $1.1 billion referenced in the press release (and the $919 million referenced in the March 2020 Press Release) accounted for sales of Vascepa for *all* uses, including the

CV indication, which undisputedly made up more than 75% of the drug's sales.

Hikma issued a final press release upon its official launch of its generic product ("the November 2020 Press Release"). J.A. 715. That press release stated:

> Hikma's FDA-approved Icosapent Ethyl Capsule product is indicated for the following indication: as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Hikma's product is not approved for any other indication for the reference listed drug VASCEPA®.

Id.

Following the approval of its ANDA, Hikma also began marketing its product on its website. There, Hikma listed its generic icosapent ethyl capsules in the "Therapeutic Category: Hypertriglyceridemia" and indicated that it was "AB" rated. J.A. 820. That rating, developed and assigned by the FDA, reflects the FDA's determination that a generic drug is therapeutically equivalent to a branded drug when the generic drug is used as labeled. It does not reflect a decision of therapeutic equivalence for off-label use. Below the product summary on the website, in small lettering, is a disclaimer that reads: "Hikma's generic version is indicated for fewer than all approved indications of the Reference Listed Drug." *Id.*

II

In November 2020, less than a month after Hikma launched its generic icosapent ethyl product, Amarin sued under 35 U.S.C. § 271(b), alleging that Hikma had induced infringement of at least claim 1 of the '537 patent, and at least claims 1 and 2 of the '861 patent. Claim 1 of the '537 patent recites:

1. A method of reducing occurrence of a cardiovascular event in a hypercholesterolemia patient consisting of:

identifying a patient having triglycerides (TG) of at least 150 mg/DL and HDL-C of less than 40 mg/dL in a blood sample taken from the patient as a risk factor of a cardiovascular event, wherein the patient has not previously had a cardiovascular event, and administering ethyl icosapentate in combination with a 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor,

wherein said 3-hydroxyl-3-methylglutaryl coenzyme A reductase inhibitor is administered to the patient at least one of before, during and after administering the ethyl icosapentate; and

wherein the 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor is selected from the group consisting of pravastatin, lovastatin, simvastatin, fluvastatin, atorvastatin, pitavastatin, rosuvastatin, and salts thereof, and

wherein daily dose of the 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor are 5 to 60 mg for pravastatin, 2.5 to 60 mg for simvastatin, 10 to 180 mg for fluvastatin sodium, 5 to 120 mg for atorvastatin calcium hydrate, 0.5 to 12 mg for pitavastatin calcium, 1.25 to 60 mg for rosuvastatin calcium, 5 to 160 mg for lovastatin, and 0.075 to 0.9 mg for cerivastatin sodium.

'537 patent, col. 15, l. 64–col. 16, l. 22.

Claims 1 and 2 of the '861 patent recite:

1. A method of reducing risk of cardiovascular death in a subject with established

cardiovascular disease, the method comprising administering to said subject about 4 g of ethyl icosapentate per day for a period effective to reduce risk of cardiovascular death in the subject.

2. The method of claim 1, wherein the subject has a fasting baseline triglyceride level of about 135 mg/dL to about 500 mg/dL and a fasting baseline LDL-C level of about 40 mg/dL to about 100 mg/dL.

'861 patent, col. 45, ll. 49–57.[5]

According to Amarin, the content of Hikma's press releases, website, and product label evidence Hikma's specific intent to actively encourage physicians to directly infringe the asserted patents by prescribing its generic icosapent ethyl product for the off-label CV indication, an indication for which Hikma did not get FDA approval. Hikma moved to dismiss under Federal Rule of Civil Procedure 12(b)(6), arguing that Amarin had failed, as a matter of law, to allege facts that Hikma had taken active steps to specifically encourage infringement.

The district court referred the case to a magistrate judge, who recommended denying the motion. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 20-1630, 2021 WL 3396199 (D. Del. Aug. 3, 2021) ("*Report & Recommendation*"). The magistrate judge concluded that, based on the totality of the allegations, which relied not only on the content of the skinny label but also Hikma's press

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[5] At oral argument, counsel for Amarin noted that the parties had agreed that the preamble of the asserted claims was limiting, such that infringement of the claims requires use of icosapent ethyl to reduce cardiovascular risk. Oral Arg. 31:13–23, *available at* https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-1169_04022024.mp3.

releases and website, Amarin had "pleaded an inducement claim . . . that is at least plausible." *Id.* at *8. Specifically, she noted that, "notwithstanding the lack of an express instruction regarding the CV indication in the 'Indications and Usage' section of Hikma's label, several other portions of Hikma's label, taken together with Hikma's public statements, instruct physicians to use Hikma's product in a way that infringes the asserted patents." *Id.* at *6. She therefore rejected Hikma's attempt to resolve the case at the pleadings stage where there was "a real dispute about what [Hikma's public statements and label] communicate to others." *Id.* at *8. Hikma timely objected to the magistrate judge's recommendation.

On *de novo* review, the district court declined to adopt the magistrate judge's recommendation and granted Hikma's motion to dismiss. *Decision*, 578 F. Supp. 3d at 643–44. The district court separated Amarin's allegations into two categories—Hikma's label and Hikma's public statements—addressing each separately. *See id.* at 645–47.

With respect to Hikma's label, the district court concluded that the warning as to side effects for patients with cardiovascular disease was "hardly instruction or encouragement" to prescribe the drug for the CV indication. *Id.* at 646. It was similarly unpersuaded by Amarin's allegation that Hikma's removal of the CV Limitation of Use would be understood by physicians as an indication that Hikma's product *had* been shown to reduce cardiovascular risk and to encourage its use for that purpose. *Id.* The court concluded as a matter of law that "[e]ven if [Amarin is] right that Hikma's label's silence regarding CV risk reduction communicates to the public that icosapent ethyl can be used to reduce CV risk, 'merely describing an infringing mode is not the same as recommending, encouraging, or promoting an infringing use.'" *Id.* (quoting, with alterations, *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed Cir. 2015)). The

district court therefore found that Hikma's label does not plausibly induce infringement. *Id.*

Turning to Hikma's public statements, the district court concluded that, although the press releases may be relevant to Hikma's *intent* to induce infringement, they did not plausibly evidence "an inducing act," a separate element for a claim arising under § 271(b). *Id.* at 647. And with respect to the website, the court determined that Hikma's advertisement of its product as AB-rated in the therapeutic category "Hypertriglyceridemia"—which the court accepted as broad enough to include infringing uses—did not "rise to the level of encouraging, recommending, or promoting taking Hikma's generic for the reduction of CV risk." *Id.* (comparing *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1336 (Fed. Cir. 2021) (per curiam) ("*GSK*"), with *Grunenthal GMBH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019)).

Because it found that Amarin's complaint failed to plead inducement based on either Hikma's label or public statements, the district court granted Hikma's motion to dismiss. *Id.* at 648.

Amarin timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a district court's grant of a motion to dismiss for failure to state a claim under the law of the regional circuit. *Yu v. Apple Inc.*, 1 F.4th 1040, 1042 (Fed. Cir. 2021). Under Third Circuit law, we review such dismissals *de novo*, accepting all well-pleaded factual allegations as true and drawing all reasonable inferences from such allegations in favor of the complainant. *See Matrix Distributors, Inc. v. Nat'l Ass'n of Boards of Pharmacy*, 34 F.4th 190, 195 (3d Cir. 2022). "We may affirm only if it is certain no relief could be granted under any set of facts that could be proven." *Warden v. McLelland*, 288 F.3d 105, 110 (3d

Cir. 2002). We apply our own law, however, with respect to patent law issues. *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999) (en banc in relevant part).

I

We begin by noting what this case is not.

Unlike the earlier Nevada litigation between the parties, this appeal is not a Hatch-Waxman case arising under 35 U.S.C. § 271(e)(2)(A), in which the alleged act of infringement was Hikma's submission of its ANDA. That is, this is not a traditional "ANDA case" in which the patent owner seeks to establish that *if* a generic manufacturer's drug is put on the market, it would infringe the asserted patent. *See, e.g.*, *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1379 (Fed. Cir. 2022); *Grunenthal*, 919 F.3d at 1337; *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1130 (Fed. Cir. 2018) ("A § 271(e)(2)(A) infringement suit differs from typical infringement suits in that the infringement inquiries are hypothetical because the allegedly infringing product has not yet been marketed." (internal quotation marks and citation omitted)). Unlike those cases, Hikma's ANDA has already been approved by the FDA and Hikma has already launched its generic product.

Furthermore, this is not a section viii case in which the patent owner's claims rest *solely* on allegations that the generic manufacturer's proposed label is "not skinny enough," such that the label alone induces infringement. *See, e.g.*, *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1370 (Fed. Cir. 2023); *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 699 (Fed. Cir. 2019); *see also Takeda*, 785 F.3d at 630. Rather, the allegations of the complaint transform this case from a pre-approval, label-only induced infringement claim to one where the alleged infringement is based on the generic manufacturer's

skinny label *as well as* its public statements and marketing of its already-approved generic product.

Put otherwise, although this case has underlying features of a traditional Hatch-Waxman case, at bottom, it is nothing more than a run-of-the-mill induced infringement case arising under 35 U.S.C. § 271(b). In such a case, we review the allegations of inducement as a whole, not piecemeal. Accordingly, we must consider whether the *totality* of the allegations, taken as true, plausibly plead that Hikma induced infringement. *See GSK*, 7 F.4th at 1338 (concluding that a skinny label, in combination with marketing materials and press releases, provided substantial evidence to support a jury verdict of induced infringement); *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 700 (Fed. Cir. 2008) (affirming a jury instruction to consider "all of the circumstances" relevant to the alleged induced infringement and concluding that "[t]aken as a whole," the record provided substantial evidence to support the jury verdict).

And critically, unlike any of our section viii-related decisions, this case does not reach us on an appeal from a post-trial motion, *see, e.g.*, *GSK*, 7 F.4th at 1323, an entry of judgment following a bench trial, *see, e.g.*, *H. Lundbeck*, 87 F.4th at 1368; *Grunenthal*, 919 F.3d at 1338, a summary judgment motion, *see, e.g.*, *HZNP*, 940 F.3d at 699, or any other motion in which the parties (and court) have the benefit of discovery. Nor does it reach us on a denial of a preliminary injunction, which we would review for an abuse of discretion. *See Takeda*, 785 F.3d at 629.

Instead, this case reaches us at its most nascent stage: on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), where we are tasked with reviewing *allegations*, not findings, for *plausibility*, not probability. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) ("[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and

that a recovery is very remote and unlikely." (internal quotation marks and citation omitted)). Accordingly, while our prior Hatch-Waxman and section viii cases are informative to the unique issues presented here, none is dispositive.

With those principles in mind, we proceed to the merits.

II

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). To state a claim for induced infringement, a patent owner must plausibly allege facts establishing that there has been direct infringement by a third party and that the alleged infringer affirmatively induced that infringement with knowledge that the induced acts constituted patent infringement. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1332 (Fed. Cir. 2016); *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc in relevant part) ("[I]f an entity offers a product with the object of promoting its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement, it is then liable for the resulting acts of infringement by third parties."). As relevant here, a generic manufacturer can be liable for inducing infringement of a patented method even if it has attempted to "carve out" the patented indications from its label under 21 U.S.C. § 355(j)(2)(A)(viii), where, as here, other evidence is asserted with regard to inducement. *See GSK*, 7 F.4th at 1338.

For purposes of this appeal, it is undisputed that Amarin's complaint sufficiently alleges (1) that healthcare providers directly infringe the asserted patents by prescribing Hikma's generic icosapent ethyl product for the off-label CV indication, and (2) that Hikma had the requisite intent and knowledge to induce that infringement. *See Decision*, 578 F. Supp. 3d at 647 ("Hikma's press releases might be relevant to intent but . . . . [i]ntent alone is not enough;

Amarin must plead an inducing act."); Oral Arg. at 11:36–47 (counsel for Hikma emphasizing that "[t]he Patent Act does not impose liability for *inferred* inducement. The statute expressly requires *actively* induced infringement."); *see generally* Hikma's Mot. Dismiss, J.A. 948–67 (arguing only that Amarin fails to allege that Hikma "actively" induced infringement).

We therefore focus narrowly on the question whether Amarin's complaint plausibly pleads that Hikma "actively" induced healthcare providers' direct infringement, *i.e.*, that Hikma "encourage[d], recommend[ed], or promote[d] infringement." *Takeda*, 785 F.3d at 631. Accepting all well-pleaded facts as true and drawing all reasonable inferences in Amarin's favor, we conclude that it does.

As an initial matter, it is undisputed that the "Indications & Usage" section of Hikma's label does not provide an implied or express instruction to prescribe the drug for the CV indication. J.A. 694. Notwithstanding that fact, Amarin alleges that other portions of the label, such as the clinical studies section, which describes statin-treated patients with the same cardiovascular event history and lipid levels covered by the asserted patents, *id.* at 702, would be understood by physicians as a teaching that the product could be prescribed to treat cardiovascular risk. *Id.* at 534–36. That is particularly so because, as Amarin alleges, the patient population for the SH indication (*i.e.*, triglyceride levels ≥500 mg/dL) overlaps with that for the CV indication (*i.e.*, triglyceride levels ≥150 mg/dL). *Id.* at 803. Amarin further argues that while the FDA's approval of the CV indication allowed Amarin to remove the CV Limitation of Use from its label, it did not so authorize Hikma. *See id.* at 528. That is, the complaint alleges that Hikma's removal of the CV Limitation of Use (despite not being approved for the CV Indication), as well as its warning of potential side effects for patients with cardiovascular disease, communicate to physicians that Hikma's generic product could be used for the off-label CV indication. In

Amarin's view, the absence of the CV Limitation of Use is particularly notable because other drugs approved for only the SH indication, *e.g.*, Lovaza®, do contain the CV Limitation of Use. *Id.* at 516.

Hikma counters that none of the portions of the label relied upon by Amarin plausibly supports the element of active inducement. In its view, Amarin's case relies on the absence of language discouraging infringement, which is contrary to law. Hikma Br. at 26–28 (citing *Takeda*, 785 F.3d at 632 n.4). According to Hikma, it only removed the CV Limitation of Use from its draft label to comply with requirements that a generic label be "the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(v). Its silence as to the product's effect on cardiovascular risk, Hikma argues, therefore cannot plausibly instruct infringement. Hikma further takes issue with Amarin's reliance on the clinical studies and warning regarding side effects in patients with cardiovascular disease, arguing that Hikma's position that such information would encourage a physician to prescribe the drug for the CV indication is implausible and "borderline frivolous." Hikma Br. at 28–30.

Taken on its own, we may agree with the district court (and Hikma) that the label does not, as a matter of law, "recommend[], encourag[e], or promot[e] an infringing use." *Decision*, 578 F. Supp. 3d at 646 (quoting *Takeda*, 785 F.3d at 631). Indeed, even the magistrate judge, who recommended denying Hikma's motion to dismiss, concluded that, "were [Amarin's] allegations based solely on the label, [Amarin's] inducement theory might lack merit as a matter of law." *Report & Recommendation*, 2021 WL 3396199, at *7. But, as the magistrate judge correctly observed, Amarin's theory of induced infringement is not based solely on the label. *Id.*; Oral Arg. at 2:15–20 (counsel for Amarin explaining that "our case is not about the label standing alone, but to be clear, we do rely on portions of the label"). Rather, it is based on the label *in combination* with

Hikma's public statements and marketing materials. We therefore turn to those materials.

Hikma's website promotes its product as AB-rated (*i.e.*, therapeutically equivalent for only the labeled indications) in the therapeutic category "Hypertriglyceridemia," a category that we accept, at this stage, as broad enough to encompass both infringing and non-infringing uses. *See* J.A. 532. On the other hand, Hikma's press releases, at least prior to November 2020, consistently referred to Hikma's product as a "generic equivalent to Vascepa®," "generic Vascepa®," or "Hikma's generic version of Vascepa®," without any indication that its product was AB-rated. *Id.* at 613, 709, 712. And the press releases further referred to Vascepa as indicated "in part" for the SH indication. *Id.* at 709, 712. Together, those statements, according to Amarin, "made clear that Vascepa® was indicated for more than one use and then identified its own product as a generic version of Vascepa®." Amarin Br. at 15. Further, the complaint alleges that, in its press releases, Hikma touted sales figures for Vascepa that Hikma knew were largely attributable to the off-label CV indication. J.A. 529, 531. Indeed, the complaint cites Hikma's own demonstrative from the Nevada litigation showing that at least 75% of sales of Vascepa were for the patented CV indication. *Id.* at 529 (citing *id.* at 803).

Those allegations, taken together with those relating to Hikma's label, at least plausibly state a claim for induced infringement. As Amarin notes, and the magistrate judge observed, many of the allegations depend on what Hikma's label and public statements would communicate to physicians and the marketplace. *See* Amarin Br. at 39–41. As we observed in *GSK*, that is a question of fact—not law—and is therefore not proper for resolution on a motion to dismiss. *See* 7 F.4th at 1330 ("Critically, the district court erred by treating this fact question—whether the [approved] indication instructs a physician to prescribe [the drug] for a claimed use—as though it were a legal one

for it to decide *de novo*."). Hikma disagrees, arguing that the factual contents of Hikma's label and public statements are undisputed, such that we can resolve this case as a matter of law, just as we have when disposing of other, similar inducement claims. Hikma Br. at 47 (citing *HZNP*, 940 F.3d at 701). We are unpersuaded.

As noted above, *HZNP* was a label-only case. *See* 940 F.3d at 702. Furthermore, and critically, that case was resolved at summary judgment, where the parties and court had the benefit of fact discovery and expert testimony. *See id.* Here, without such discovery and testimony, we must accept as true Amarin's allegations and all reasonable inferences supported by those allegations. Applying this standard of review, we find it at least plausible that a physician could read Hikma's press releases—touting sales figures attributable largely to an infringing use, and calling Hikma's product the "generic version" of a drug that is indicated "in part" for the SH indication—as an instruction or encouragement to prescribe that drug for *any* of the approved uses of icosapent ethyl, particularly where the label suggests that the drug may be effective for an overlapping patient population. Further, it is at least plausible that a physician may recognize that, by marketing its drug in the broad therapeutic category of "Hypertriglyceridemia" on its website, Hikma was encouraging prescribing the drug for an off-label use. To be sure, the website clearly labels the drug as AB-rated, indicating generic equivalence for only labeled uses.[6] But we decline to hold, at this stage, that one notation of the AB rating on Hikma's website—and nowhere else—insulates it from a claim for induced infringement, particularly where we have upheld

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[6] And, as noted above, the website includes an express disclaimer that Hikma's product is FDA-approved for fewer than all uses of Vascepa.

jury verdicts based, in part, on marketing materials containing similar language. *See GSK*, 7 F.4th at 1335–36.

Hikma challenges Amarin's reliance on *GSK*, arguing that in that case we expressly declined to hold that calling a product a "generic version" or a "generic equivalent" is enough for induced infringement. 7 F.4th at 1336 ("The dissent criticizes our analysis, claiming that we have weakened intentional encouragement because 'simply calling a product a "generic version" or "generic equivalent"—is now enough.' That is not our holding or the facts." (internal citation omitted)). In Hikma's view, a reversal in this case would run afoul of that clear limitation of *GSK* and would realize the concerns raised in its dissent. We disagree. Not only does this case differ procedurally from *GSK* (which was decided on a post-trial motion for judgment as a matter of law), but it also differs factually. There, we held that substantial evidence supported the jury's finding that the generic manufacturer's label had unsuccessfully carved out the patented use. *See id.* at 1338. Accordingly, because the label itself taught an infringing use, it was reasonable for the jury to find that the generic manufacturer's marketing of its product as an "AB rated generic equivalent" encouraged physicians to prescribe the drug for the infringing use instructed by the label. *Id.* at 1335–36.

Those, however, are not the facts of this case. Hikma's press releases do *not* refer to its product as AB-rated. If they had, Hikma's distinction of *GSK* may have been more persuasive as even Amarin seems to agree that the label alone does not instruct infringement. Instead, Hikma's press releases broadly refer to the product as a "generic version" of Vascepa and provide usage information and sales data for the brand-name drug from which it is plausible that a physician could discern an encouragement to use the generic for purposes beyond the approved SH indication. This conclusion—that the totality of the allegations plausibly states a claim for induced infringement—does

not evoke the concern espoused by the dissent in *GSK*, much less hold, that a mere statement that a generic manufacturer's product is the "generic version" of a brand-name drug is enough to be liable for induced infringement. Nor does it run afoul of our observation in *GSK* that "generics could *not* be held liable for merely marketing and selling under a 'skinny' label omitting all patented indications, or for merely noting (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug." *Id.* at 1326. Amarin has pleaded that Hikma did much more than call its product a "generic version" of Vascepa. Taking those allegations as true, Hikma has neither "merely" marketed its drug under a skinny label that omits all patented indications nor "merely" noted that the FDA has rated its drug as AB-rated. Though the merits of Amarin's allegations have not yet been tested or proven, we cannot say at this stage that those allegations are not at least plausible.

Finally, we reject Hikma's inflated characterizations that a reversal in this case would "effectively eviscerate section viii carve-outs." Hikma Br. at 48; Oral Arg. at 20:10–26 (counsel for Hikma asserting that "the entire industry is watching this case. It's a test case . . . . And if merely calling a generic product a 'generic version' is sufficient to get past the pleading stage, section viii is dead."). Our holding today is limited to the allegations before us and guided by the standard of review appropriate for this stage of proceedings. We continue to acknowledge, as we did in *GSK*, that there is a "careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs." 7 F.4th at 1326. That balance benefits both brand manufacturers and generic manufacturers alike. What we can also say is that clarity and consistency in a generic manufacturer's communications regarding a drug marketed under a skinny label may be essential in avoiding liability for induced infringement. Here, because Amarin has plausibly pleaded that, despite its section viii carve-out, Hikma

has induced infringement of the asserted patents, Hikma is not entitled, at least at this stage, to benefit from that balance.

CONCLUSION

For the foregoing reasons, we hold that Amarin has plausibly pleaded that Hikma has induced infringement of the asserted patents. We therefore reverse.

REVERSED

CERTIFICATE OF COMPLIANCE

This petition complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(b)(2)(A) because it contains 3,886 words.

This petition complies with the type-face and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5), 32(a)(6), and 32(c)(2). This petition has been prepared in a proportionally spaced typeface using Microsoft Office Word in 14-point Times New Roman.

Dated: August 22, 2024

/s/ Charles B. Klein
CHARLES B. KLEIN
Attorney of Record for
Defendants-Appellees